



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/593,225

07/02/2007

Maria Elena Sarmiento Garcia San Miguel

LEXSA.P40

7041

28752 7590 07/16/2008
LACKENBACH SIEGEL, LLP
LACKENBACH SIEGEL BUILDING
1 CHASE ROAD
SCARSDALE, NY 10583

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

07/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,225	Applicant(s) MIGUEL ET AL.	
	Examiner Mark Navarro	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 13-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment filed May 13, 2008 has been received and entered. Claims 6-12 and 17 have been cancelled and new claims 18-20 have been added. Consequently, claims 1-5, 13-16 and 18-20 are pending in the instant application.

Election/Restrictions

Newly submitted claims 18-20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 18-20 are drawn to a method of using the product of claims 1-5, and 13-16. However, the unique special technical feature of the invention is the product (immunogenic composition of *Streptomyces*) which is taught by the prior art (e.g., Tremblay et al). Accordingly, the method of using the product is an independent and distinct invention from the product, when the product is disclosed in the prior art.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18-20 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

1. The objection of claim 16 for failing to end with the punctuation mark of a "period" is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 101

2. The rejection of claims 6-12 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the cancellation of said claims.

Claim Rejections - 35 USC § 112

3. Claims 1-5 and 13-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide vaccine compositions is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1-5 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tremblay et al is maintained.

Applicants are asserting that Tremblay et al fails to disclose “live” “wild strains” of

Streptomyces and administering same for preventing tuberculosis.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants assert that Tremblay et al fails to disclose "live" strains. However, Applicants are respectfully directed to the teachings of Tremblay et al. Tremblay et al disclose of the heterologous production of two Mycobacterial antigens by Streptomyces lividans, an exceedingly difficult job to do with a "dead" strain. Clearly, the strains would only be able to produce a recombinant protein if living. Accordingly, the strain disclosed by Tremblay et al is clearly "alive."

Second, Applicants assert that Tremblay et al fails to disclose "wild" strains. As set forth on Applicants own specification (page 6) the "wild strain" used in the present invention is a "non-pathogenic industrial stain, widely used in the production of medicines for man." (Page 6, lines 1-2). Applicants will note that Tremblay et al used Streptomyces lividans IAF10-164 for recombinant expression. (See page 44).

Kebir et al (Biochimica et Biophysica Acta Vol. 1491 Issues 1-3, April 25, 2000, pp 177-184) set forth that Streptomyces is a "non-pathogenic" genus. (See page 3 of 15).

Accordingly, the Streptomyces lividans strain employed by Tremblay et al is a "non-pathogenic industrial strain" and clearly was used for "the production of antigens." Consequently, the Streptomyces lividans strain used by Tremblay was both live and wild, and meets each and every limitation set forth in the claims.

The claims are directed to an immunogenic composition obtained from Streptomyces characterized in that they comprise as active components of one or more wild strains of Streptomyces genus or mutant or recombinant strains derived from such strains, as well as an adequate excipient.

Tremblay et al (Can. J. Microbiol. Vol. 48, pp 43-48, 2002) disclose of the heterologous expression of two major antigenic protein from Mycobacterium tuberculosis in Streptomyces lividans hosts. (See abstract). Tremblay et al further disclose of the Streptomyces lividans strains combined with xylose (adequate excipient). (See page 45).

Accordingly, Tremblay et al disclose of each and every limitation recited in the claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
July 14, 2008